

Minutes
Health Research Advisory Committee
October 8 and 9, 2009
Hilton Garden Inn, Salon A & B
Philadelphia, Pennsylvania

Committee Members Present:

Dwight Davis, MD, Professor, Pennsylvania State University College of Medicine and Director of Cardiac Rehabilitation, Hershey Medical Center
Lewis Kuller, MD, DrPH, Professor of Epidemiology and University Professor of Public Health, Graduate School of Public Health, University of Pittsburgh
Arthur Levine, MD, Senior Vice Chancellor for Health Sciences and Dean of the School of Medicine, University of Pittsburgh (present on October 9th only)
Michael Parmacek, MD, Herbert C. Rorer Professor of Medical Sciences and Director of the Penn Cardiovascular Institute, University of Pennsylvania School of Medicine
Michael V. Seiden, MD, PhD, President and Chief Executive Officer, Fox Chase Cancer Center
Kim Smith-Whitley, MD, Assistant Professor, Department of Hematology, The Children's Hospital of Philadelphia (present on October 9th only)
Lisa Staiano-Coico, PhD, Provost and Senior Vice President for Academic Affairs, Temple University

Department of Health (DOH) Staff:

Cathy Becker, MPH, Health Research Program Manager, Bureau of Health Statistics and Research
Diane Kirsch, RHIA, CTR, Public Health Program Administrator, Health Research Program, Bureau of Health Statistics and Research
John Koch, Program Analyst, Health Research Program, Bureau of Health Statistics and Research
Patricia W. Potrzebowski, PhD, Director, Bureau of Health Statistics and Research
Robert Torres, JD, Deputy Secretary for Administration

Others in Attendance:

Gregory P. Adams, PhD, Member, Fox Chase Cancer Center
Martin W. Adler, PhD, Director, Center for Substance Abuse Research, Temple University
Kelly Allison, PhD, Assistant Professor, University of Pennsylvania
Susan G. Amara, PhD, Detre Professor and Chair of Neurobiology, University of Pittsburgh
John T. Anthony, Project Associate, Pennsylvania State University
Katrina Armstrong, MD, MS, Associate Professor of Medicine and Director, Division of General Internal Medicine, University of Pennsylvania
James E. Barrett, PhD, Professor and Chair, Department of Pharmacology and Physiology, Drexel University College of Medicine
Sheri A. Berenbaum, PhD, Professor of Psychology, Pennsylvania State University

Dawn A. Bonnell, PhD, Director, Nano/Bio Interface Center, University of Pennsylvania
Anna Childress, PhD, Director, Neuroimaging and Conditioned Factors Division, Penn/VA
Addiction Treatment Research Center, University of Pennsylvania School of Medicine
Kevin Conway, PhD, Deputy Director, Division of Epidemiology, Services, and Prevention
Research, National Institute of Drug Abuse
Toby K. Eisenstein, PhD, Professor, Temple University School of Medicine
Paul J. Eslinger, PhD, Professor/Director of Clinical Neuropsychology and Cognitive
Neuroscience Programs, Pennsylvania State University College of Medicine
Jennifer Fassbender, MS, Senior Research Project Manager, University of Pennsylvania School
of Medicine
Robert Gage, Assistant Vice President and Director, Sponsored Research Programs, Temple
University
Jean Givey, Newtown Square
Mark T. Gladwin, MD, Chief, Pulmonary and Critical Care Medicine, University of Pittsburgh
School of Medicine
Piotr Grodzinski, PhD, Program Director, National Cancer Institute (NCI) Alliance for
Nanotechnology in Cancer
Michael J. Hall, MD, MS, Director, Gastrointestinal Tumor Risk Assessment Program, Fox
Chase Cancer Center
Steven G. Hughes, PhD, Associate Professor and Director, Aquaculture Research and Education
Center, Cheyney University
Leslie Hurtig, MPA, Vice President, Behavioral Health Services, Public Health Management
Corporation
Christine Keating, PhD, Associate Professor of Chemistry, Pennsylvania State University
Mark Kester, PhD, G. Thomas Passanti Professor of Pharmacology, Penn State Hershey Medical
Center
Mohammad F. Kiani, PhD, Professor and Chair, Department of Mechanical Engineering, Temple
University
James P. Kimmel, Jr., JD, Chief Operating Officer, Peerstar LLC
Kimberly C. Kirby, PhD, Senior Scientist & Director of Behavioral Interventions Research,
Treatment Research Institute
Linda C. Knight, PhD, Professor, Department of Diagnostic Imaging, Temple University School
of Medicine
Robert J. Levy, MD, Pediatric Cardiologist, Children's Hospital of Philadelphia
Paul M. Lieberman, PhD, Professor, Wistar Institute
Delroy M. Loudon, PhD, Director, Office of Research, Development Planning and Coordination,
Lincoln University
Thomas P. Loughran, Jr., MD, Director, Penn State Cancer Institute, Penn State Hershey
Medical Center
Margaret C. McDonald, PhD, MFA, Associate Vice Chancellor for Academic Affairs, University
of Pittsburgh
Larry W. Moreland, MD, Chief, Margaret J. Miller Endowed Professor for Arthritis Research,
University of Pittsburgh
Chris Murray, PhD, Professor of Chemistry and Materials Science and Engineering, University
of Pennsylvania

Jenae Neiderhiser, PhD, Liberal Arts Research Professor, Department of Psychology,
Pennsylvania State University

Charles P. O'Brien, MD, PhD, Professor and Vice-Chair of Psychiatry, University of
Pennsylvania School of Medicine

Carlo G. Pantano, Director of the Materials Science Research Institute, Pennsylvania State
University

Ian Paul, MD, Associate Professor of Pediatrics, Penn State University College of Medicine

Connie Pechura, PhD, Executive Director, Treatment Research Institute

Vanaja V. Ragavan, MD, Founder, President, and CEO, Aviana Molecular Technologies, Inc.

Matthew K. Robinson, PhD, Associate Member, Fox Chase Cancer Center

Diane Rosetsky, MEd, Grants and Contracts Coordinator, Jefferson Kimmel Cancer Center

Joy Soleiman, MPA, Clinical Administrator, Jefferson Kimmel Cancer Center

Robert Turrisi, PhD, Professor, Department of Biobehavioral Health, Pennsylvania State
University

Flordeliza S. Villanueva, MD, Associate Professor of Medicine, University of Pittsburgh

Joanne Yeh, PhD, Associate Professor of Structural Biology, University of Pittsburgh

Call to Order

Deputy Secretary Robert Torres called the meeting to order at 9:02 a.m. on Thursday, October 8, 2009 in Salon A-B of the Hilton Garden Inn in Philadelphia, Pennsylvania. Mr. Torres welcomed Committee members and others to the meeting and stated that he had been designated by the Secretary to chair the meeting and represent the Secretary in the Secretary's absence. He introduced Dr. Seiden to the committee. Dr. Seiden was appointed by the Speaker of the House to complete the remainder of Dr. Young's term of office. Mr. Torres indicated that the primary purpose of the 2-day meeting was to hear recommendations from invited speaker regarding potential health research priorities and to discuss and determine the areas of research to be considered for next year's priorities.

Minutes of the December 12, 2008 Meeting

A motion was made by Dr. Staiano-Coico and seconded by Dr. Davis to accept the minutes of the meeting held on December 12, 2008. The minutes were approved by all Committee members.

Health Research Program Update

Dr. Potrzebowski provided an update on staff activity in six areas. (1) Annual report to the legislature: The program is currently working on compiling the annual report, which will be submitted to the legislature and posted on the Department's Web site. (2) Formula grants: The Department awarded 32 formula grants for the state fiscal year that ended in June and expects to issue the RFA for this year's grants in October. (3) Research Priorities: The Department emailed the call for testimony on the research priorities in February to 1,200 contacts. The testimony is posted on the CURE Web site (www.health.state.pa.us/cure). The Secretary and Committee requested information on nanotechnology and a fact sheet containing that information was provided to Committee members. (4) 2008 Nonformula grants: In June the Department awarded

two nonformula grants for autism spectrum disorders and two grants for antibiotic resistance. (5) 2009 Nonformula RFA: The RFA was advertised on the Department of General Services' Web site on July 27th. Nine letters of intent were received for cancer vaccines and six letters of intent were submitted for blindness and visual impairment. (6) Performance review: Interim performance reviews were conducted for two nonformula grants on gene environment interactions and two vaccine development grants. Final performance reviews were completed on the 47 formula grants and the 2003 pregnancy outcomes and lung disease nonformula grants. A handout summarizing program and performance statistics for the first eight years of the CURE program was posted on the CURE Web site and provided to the Committee. Cathy Becker indicated that \$717 million, the amount of funds leveraged by grantees to date, includes indirect and direct costs from all sources of funds.

Invited Public Testimony on Research Priorities for State Fiscal Year 2010-2011

Mr. Torres introduced the session by describing the process of selecting the invited presenters. First, the Department issued an invitation for written testimony on health research priorities for 2010-2011. Ten persons of the 37 who submitted written testimony were selected by the committee members to provide testimony at the meeting.

The names of the presenters, a brief summary of the research priority presented, and responses to questions raised by the Committee are summarized below.

- Dr. Katrina Armstrong, University of Pennsylvania, discussed the potential of genomics medicine to improve treatment outcomes, identified the need for prospective studies to assess the effectiveness of genomics medicine, and provided examples of applications to the treatment of tobacco dependence, breast cancer, lung cancer and melanoma. In response to questions about how Pennsylvania funding can focus on areas not funded by NIH, Dr. Armstrong indicated that NIH funds the discovery of genomics tests, but funds are needed for small clinical trials to provide evidence of clinical outcomes. Dr. Seiden asked if there were examples of how genomics has changed primary care in non-cancer areas.
- Dr. Mark Gladwin, University of Pittsburgh, stated that as more persons with Sickle Cell Disease (SCD) survive to adulthood they suffer from vascular complications, including pulmonary hypertension, and none of the currently FDA-approved drugs to treat this condition are effective for persons with SCD. Potentially in the state there are 3,000 adult persons with SCD who are not being treated in the specialty centers. NHLBI has dropped funding for the centers of excellence because they were concerned about the quality of the science and that funds were being used for infrastructure rather than research.
- Dr. Larry Moreland, University of Pittsburgh, indicated that 65% of Pennsylvanians over age 65 have arthritis. He focused his remarks on rheumatoid arthritis (RA), which affects 1% of adults, and indicated that there is a need for comparative effective research of multiple therapies and prospective, longitudinal cohort studies which include biorepositories. When asked how Pennsylvania funds should be focused, Dr. Moreland indicated that there is a need for registries and NIH will not fund registries.
- Dr. Ian Paul, Pennsylvania State University, reviewed statistics showing the increase in the prevalence of obesity and advocated for research on the primary prevention of obesity with a focus on pregnancy and early life. He referred to evidence of the effectiveness of

interventions designed to teach mothers how to feed, soothe and calm their infants. Dr. Kuller asked what environmental factors may be causing the epidemic. Dr. Paul noted that there are more Hispanics, who have a higher prevalence of overweight, in the general population. There is an income disparity and factors such as access to unhealthy food and physical activity resources play a role.

- Mr. Kimmel, Peerstar LLC, asked whether the compulsion to seek revenge and the compulsion to use drugs are motivated by the same neurobiological factors. Dr. Eslinger, Pennsylvania State University, advocated for experimental research to look at brains of people when they are making decisions to determine if the same neurobiologic factors mediate revenge seeking and addictive behaviors. Dr. Kuller mentioned a recent publication in *Science* about a clinical trial that used a dietary approach (omega 3 fatty acids) to modify violent behavior. The argument is that youth, who become violent, may have suffered from severe nutritional deficiencies early in life, such as omega 3, which is linked to brain development. Dr. Staiano-Coico raised the concern that this avenue of research may lead to profiling.
- Dr. Kimberly Kirby, Treatment Research Institute, raised two research issues related to substance abuse treatment. (1) How can models of chronic disease care, including long term monitoring, be applied to improve substance abuse treatment? Typically patients are treated in an acute care setting, where treatment ends when patients are discharged. (2) How can the use of empirically-supported treatments (ESTs) by community-based providers be increased? Dr. Kirby pointed out that fewer than 10% of providers in one study used two ESTs for where there is the strongest empirical support.
- Dr. Paul Lieberman, Wistar Institute, stated that 17-18% of all human cancers are attributable to chronic viral infections. Funding is needed to gain a better understanding of the immunological response, and for research on vaccine development, antivirals, detection of new and low abundance viruses, and monoclonal antibodies. In response to Dr. Seiden's question about the likelihood of discovering new viruses related to cancer, Dr. Lieberman indicated that it is likely that many viruses cannot be cultured and that the true percentage of cancers attributable to viral infections might be closer to 25%.
- Dr. Flordeliza Villanueva, University of Pittsburgh, stressed the use of molecular imaging to identify disease precursors. Molecular imaging can identify biomarkers of disease activity, and adjust treatment regimens. In response to questions about the best modality to use and how to focus Pennsylvania funds so they do not duplicate NIH's funding, Dr. Villanueva indicated that there is no one best method; each method makes a unique contribution and that there is a need for translational research, for clinical trials. One of the issues is that the cost is high, \$5,000-6,000/patient for PIB testing, for example.
- Dr. James Barrett, Drexel University, indicated that 70% of terminally ill cancer patients experience unrelieved pain. There is a need to develop new therapies since management by opioids and other treatments is inadequate. In response to a question about how to focus research in this area, Dr. Barrett suggested research involving academia and industry, focusing on novel targets, developing new animal models and starting with small, focused studies.
- Dr. Michael Hall, Fox Chase Cancer Center, stated that Pennsylvania has the fifth highest incidence of gastrointestinal cancer in the nation. There are disparities in access to genetic risk assessment. He recommended funding for research to determine the feasibility of a no-cost, community-based risk assessment model. Dr. Seiden asked if there is any literature in

gastrointestinal cancer for this model. Dr. Hall indicated that there is no literature on gastrointestinal cancer; all research is on breast cancer genetic risk assessment. Dr. Kuller commented that the first research issue to consider would be the need to determine the number of colorectal deaths under age 60 that are familial related.

Minority Training Initiative

Mr. Torres stated that the Requests for Applications (RFAs) for nonformula health research funds have included a requirement for the training and involvement of minority students in the research project. The purpose of this session was to an opportunity for Committee members to hear about the experiences of the applicants and their collaborators in implementing this aspect of the research project and discuss possible changes for the Department to consider in future health research grants. During this summer, the Department asked the principal investigators of the 2005, 2006 and 2007 nonformula grants and administrative personnel at their institutions to respond to a survey designed to assess the benefits of the minority training requirement, the impact of the training and research involvement on the career choices of participants, the challenges faced in implementing the requirement, and strategies used to overcome the challenges. Cathy Becker summarized the results of the survey. Her presentation and presentations made by representatives of institutions involved in the effort are summarized below.

- Cathy Becker indicated that 13 of the 14 principal investigators (PIs) responded to the survey and reported that 240 student research trainees and interns were recruited to participate in their research projects. Of these, slightly over half were either African American or Hispanic of any race. It appeared from the responses to questions about the trainees' roles and length of time spent on the projects that the RFA requirement for involving students in a substantive and meaningful way was met. However, it is unclear whether the training experience inspired students to pursue careers in medical and health research. Effective recruitment strategies included word-of-mouth promotion by faculty and trainees, having minority investigators in project leadership roles, providing job description and offering interesting/challenging tasks. Recruitment challenges included the lack of public transportation between minority institutions and applicant institutions, lack of time during academic year, more lucrative jobs elsewhere, limited pool of post baccalaureate minority students, and communication issues between institutions. In response to several questions Ms. Becker indicated there was no expectation that the PIs attempt to maintain a long-term relationship with trainees, and that the Department does not have data on the number of under-represented students going into science at the applicant institutions.
- Dr. Steven Hughes indicated that Cheyney University participated in 7 grants since 2005 and more than 30 students are involved in or have completed internships. Some of the limitations on collaboration at Cheyney University included limited number of faculty, limited on-campus facilities and equipment, heavy teaching loads and no reward for research. Limitations on collaboration at other institutions included heavy budgets associated with clinical and lab studies and lack of understanding of cultural diversity. He concluded that the program has benefited their institution and recommended that funds be used to for infrastructure and to hire faculty at Cheyney. Dr. Davis commented that it appears that the program has had a positive impact despite the challenges it faced. In response to a question

about future directions, Dr. Hughes said that he would like to see more of their students going into post-baccalaureate programs as a bridge to masters or doctoral programs.

- Dr. Delroy M. Loudon stated that Lincoln University has been a collaborator on two research grants. As part of these projects they developed a memorandum of understanding with the institutions and advisory committees containing representatives from the applicant institution and Lincoln University. Lincoln University's objectives include training both faculty and students. All of the seven students who participated in internships at The Children's Hospital of Philadelphia have gone on to graduate programs or medical school. They team each student up with a mentor. Lincoln University has developed new courses as a result of the collaborations. The benefits of this program to Lincoln University include the development of a research infrastructure at Lincoln University, membership in the Council of Undergraduate Research, strengthened library resources, increased faculty grant writing and the award of external funding (grants for \$4 million with Penn State and several grants with Fox Chase). Challenges include timelines and institutional cultures. Dr. Loudon would like to see money for administration of these training programs.
- Ms. Jennifer Fassbender presented information on the merits of the minority training program from the standpoint of their obesity research project at the University of Pennsylvania. Their minority training program involved ten students from Cheyney University and other universities. Students became more aware of health research as a career option. Three of these students started public health graduate programs and they hired two students who are considering graduate school. Some of the challenges included recruiting students who were interested in the project and transportation. Recommendations for the future included allowing students to work on research projects that are not part of the funded research project, providing opportunities for students to participate in research projects on the Cheyney campus and encouraging interactions at Cheyney University among students involved in all the projects.
- Dr. Margaret McDonald provided information on the University of Pittsburgh's experience with the minority training requirement. During the past year nonformula funding enabled the University to include four students from Cheyney and Lincoln Universities in their Summer Premedical Academic Enrichment Program and to place them in research projects. Nonformula funds also allowed the University to develop a postbaccalaureate, pre-doctoral preparation program for students and enrol two students. Some of the challenges facing their efforts include the fact that grant funds are not sufficient to cover all of the costs for minority training. Cheyney and Lincoln Universities have limited research resources and pools of students interested in biomedical and health research. Most minority-serving community-based organizations are not focused on research. Also, the RFA requirements are not synchronized with academic calendars.

Nanotechnology Workshop

Mr. Torres stated that during the discussion of last year's research priorities, the Committee requested that we hold a workshop on nanotechnology to hear what the critical research issues are. Nanotechnology investigators were asked to address the following questions:

- What are the specific hypothesis-driven biomedical and clinical research questions that need to be addressed?
- What areas of nanotechnology research should be excluded from consideration?

- What types of nanotechnology or nanomaterials are ready for clinical trials?
- What types of nanotechnology or nanomaterials exist currently that could be applied and tested in a population over a 4-year period?

Presentations

- Dr. Piotr Grodzinski, National Cancer Institute (NCI) Alliance for Nanotechnology, pointed out that, unlike the reductions in heart disease and other conditions, there has been no improvement in cancer mortality over the past 50 years, which underscores the need for new approaches to cancer prevention and treatment. Nanotechnology will allow for the development of in-vitro and in-vivo sensors, novel imaging contrast agents and platforms for localized therapies, which would contribute to earlier diagnostics and reduced side effects of therapy. There are currently 77 clinical trials using nanoparticle-based formulations, but bringing nanotechnology solutions into practice is very expensive. NCI has funded eight centers for nanotechnology and has been approved for the next 5-year cycle of funding. In response to various questions from the committee, Dr. Grodzinski stated that the optimal size grant is \$2½-3 million for 5 years; less than 5 years will not have an impact. Nanotechnology can be used for finding biomarkers. Nanotechnology could be used to detect circulating tumor cells (CTC), which have a low ratio to normal cells. The bulk of investigations are focusing on therapeutics, but NCI is trying to focus more on diagnosis and prevention.
- Dr. Robert Levy, Children's Hospital of Philadelphia, announced that *Nature* will be publishing next week the results of research on magneto nanosensors; this research represents a break through, which will lead to the early detection of new biomarkers. Dr. Levy addressed the use of biodegradable therapeutic nanoparticles for local delivery. They are a cutting edge therapeutic delivery system, which was recently approved for clinical use. Biodegradable therapeutic nanoparticles offer sustained action, can be localized and targeted, can overcome toxicity issues, can pass through cancer cell membranes and lodge in tumor cells, and are compatible with drug, molecular and stem cell therapies. He summarized research on the use of magnetic nanoparticles to prevent reobstruction of stents used to treat obstructive vascular disease. Restenosis is associated with stent failure. Rat carotid stent angioplasty studies demonstrated a 60% reduction in restenosis using magnetic nanoparticles.
- Dr. Mohammad Kiani, Temple University, stated that the biggest potential applications for nanoparticles are targeted drug delivery and biofluidics devices. He explained how liposomes can be used to target chemotherapeutics to irradiated tumors and to deliver drugs for growing new microvasculature in post-MI tissue. They have developed a microvascular network on a chip which can be used for in-vitro testing of drugs. Under a recent NASA grant award, they are going to attach nanoparticles on the surface of the irradiated cells for the purpose of detecting radiation-damaged cells during deep space flight. This approach can be used to detect cancer cells from biopsies and CTCs, and they received a grant for this purpose.
- Dr. Linda Knight, Temple University, addressed the use and benefits of using non-toxic, biodegradable nanoparticles for imaging and therapy, and she provided examples of their use in research. Monocrystalline Iron Oxide Nanoparticles (MIONs) has been used as an imaging agent to show tumors in rats and it has successfully made it to clinical trials. Clinical studies used ferumoxtran nanoparticles as an imaging agent to monitor the treatment of atherosclerotic plaques. Pre-clinical studies have also treated atherosclerosis with targeted anti-angiogenic nanoparticles.

- Dr. Thomas Loughran, Penn State Cancer Institute, reported that Penn State used formula funds for nanotechnology projects, which generated a 30-fold return on investment in terms of NCI grants received. Penn State designed a non-toxic nanoparticle (jacket) in which an imaging agent or therapeutics can be inserted. NCI funded a national nanotechnology characterization laboratory to develop nanotechnology-based therapeutics, and Penn State developed three nanotechnologies that are in various stages of acceptance for pre-clinical evaluation by the NCI lab. There is data in vivo that animals with pancreatic cancers can be cured with siRNA nanotechnology. Penn State just formed a Center for Nanomedicine and Materials to further collaborative research work among three institutes within the university. He added that this area of research is a great opportunity for economic development in Pennsylvania; 40-80 biootech companies have been formed in the state, including Keystone Nano, a Penn State startup company.
- Dr. Vanaja Ragavan, Aviana Molecular Technologies (AMT), stated that her company is developing a piezoelectric affinity biosensor to diagnose infectious diseases at the point of care. This sensor will increase sensitivity and specificity and save time. She indicated that they are focused on getting the technology to market in three years and are looking for support.
- Dr. Matthew Robinson, Fox Chase Cancer Center, stated that there is a dearth of validated cancer biomarkers that can be used clinically to define the presence of cancer and predict and monitor response to therapy. He is working with investigators at the University of Pennsylvania to develop new nanotechnology platforms using Single-wall Carbon Nanotube Transistors (SWNT) and piezoelectric resonant nanoelectromechanical sensors (NEMS) that would be used to detect cancer biomarkers in serum and urine.
- Dr. Gregory Adams, Fox Chase Cancer Center, is studying two nanotechnologies, in collaboration with Drexel University, Temple University and Solixia Biotech, a University of Pennsylvania start up company. The first technology, Piezoelectric microcantilever sensors (PEMS), can provide sensitive real-time biomarker detection in biological fluids. The results of a study following eight patients showed that PEMS biosensors were able to detect a subclinical immune response to anti-tumor monoclonal antibody therapy in six patients -- responses which could not be detected by the gold standard ELISA detection technology. The second area of research involves the development of targeted radioactive nanoparticles (HotDots), which have the potential to penetrate more deeply into the tumor and can be used for targeted imaging and therapeutics. While some of the new technologies have made it into clinical use, there is a pressing need for research to validate these approaches in larger scale clinical studies.
- Dr. Dawn Bonnell, University of Pennsylvania, stated that the field of nanotechnology goes beyond the development of nanoparticles. Research is needed in four areas: biomedical research, diagnostic strategies, therapeutic strategies and disease prevention. Regarding disease prevention, nanotechnology is currently available in a wide range of consumer products. A recent study from the Wilson Institute indicated the need for toxicity studies. There is also a need for behavioral studies on risk evaluation, risk perception and exposure avoidance. Pennsylvania has tremendous strengths for nanotechnology, including a highly developed fundamental research infrastructure, research facilities that don't exist elsewhere, collaborative university-based device technology programs and world class expertise on nanoparticles. Outcomes of investment in this area include advances in basic science, the development of point-of-care device technologies, commercialization opportunities, and a

better understanding of risk perception. Commercialization of device technologies via licensing and start up companies is realized in a shorter time frame than many therapeutic strategies.

- Dr. Joanne Yeh, University of Pittsburgh, stated that materials at the nanoscale behave differently than at the macro level and there is a need to study single molecules. One of the goals of this research is to enable measurements in the cells of patients in the doctor's office. Investments in nanotechnology research will lead to enhancements in fundamental science. They have developed biosensors for small molecules and Dr. Yeh provided examples of work done on asthma and prostate cancer. She also mentioned that materials manufactured at the nanolevel can become toxic because they can penetrate cells. On the other hand, this suggests their potential to be made into chemotherapeutic materials.
- Dr. Christine Keating, Pennsylvania State University, stated that the driving force for work in this area is the hypothesis that early detection and treatment of disease will increase survival and quality of life. She recommended that research focus on cancer. An example of nanotechnology already in use is golden nanospheres, which are used in flow assays and currently for pregnancy testing. They have developed and are using an assay involving nanowires, which can detect multiple viruses at the same time and does not require washing of the sample. The next challenge in diagnostics is bioelectronics, i.e., how to combine modern computer chip technology with biosensing. Exciting targets for therapeutics are nanoliposomes. They are already on the market, but still require study to solve problems such as how to encapsulate a new drug in a nanoliposome, improved drug loading, better targeting and reduced toxicity. The final technology mentioned was calcium phosphate nanocomposite particles, which are also called nanojackets. These are bioresorbable and they are close to the point of clinical trials. Penn State is part of the NSF (National Science Foundation) National Nanotechnology Infrastructure Network where anyone inside or outside the state can come and work. This is one example of the good infrastructure in Pennsylvania for this type of research.
- Dr. Chris Murray, University of Pennsylvania, addressed his interest in providing highly tailored, inorganic nanocrystals for targeted biosensing and therapeutics. Partnerships with Pennsylvania's existing specialty chemical and pharmaceutical companies would yield economic as well as human benefits. He stated that there are health and environmental concerns with nanomaterials, but the available studies do not use the best available materials so there is a need to use good science and the best available nanomaterials to assess toxicology and impact on the environment. Synergies for Pennsylvania with its leadership in specialty chemicals, pharmaceuticals and medicine make this a compelling opportunity.

Discussion

Dr. Seiden raised two issues. Engineering and material science has outpaced biology with its ability to measure phenomenon at picomolar concentrations while there are no known biomarkers at this level. Also, FDA and regulatory agencies have not determined the appropriate processes for approving nanotechnology. Dr. Kuller asked if anyone would be able to respond to an RFA requesting research projects to evaluate the use of nanotechnology in diagnostics and therapy. Dr. Murray responded that the FDA is treating some of the nanomaterials as devices, which has sped up the approval process. Magnetic hyperthermias have already been approved and are being used for imaging. However, we need to determine how these materials can now be used for therapeutics. Dr. Kuller asked if the technology can be used to identify exposures to

environmental toxins. Dr. Murray responded that there is a need for good science to understand the full implications of the effects of nanomaterials in the environment. Dr. Kester added that they will have the ceramide nanoliposomes in clinical trials that within 12-16 months, IL13 nanoliposomes in clinical trials in two years and the calcium phosphate nanoparticles in trials within 2-2½ years. There are FDA approved drugs, doxil, which is the standard of care for some types of breast cancer. The FDA is working with nanotechnology companies on the reuse of already approved drugs. Dr. Parmacek noted that NSF and NCI have invested millions in nanotechnology and asked how our approximately \$20 million would not be redundant and if there is a funding gap that our funds could fill. Dr. Adams responded that the usual funding sources for nanotechnology, Ben Franklin Partnerships and NTI, are concerned that their funding is ending this year. However, the big hurdle is getting to clinical trials, they need funds for fabrication of materials to meet GMP (Good Manufacturing Practices) so they can conduct the clinical trials with more than 10 patients. Dr. Kester added that they can apply for funding for pre-clinical studies, but there is a gap between the pre-clinical studies and taking it to the clinic. This gap has typically been filled by venture capital and investments by small companies, but the state should bridge that gap. Dr. Yeh added that there should be a requirement for involvement of investigators from multiple institutions.

Recess and Reconvening of the Committee

The meeting recessed at 5:15 p.m. on October 8th and reconvened at 9:05 a.m. on October 9th.

Substance Abuse Workshop

Mr. Torres stated that the Department organized a workshop on substance abuse in response to the Committee's request last year. Presenters were asked to focus on drug and/or alcohol addiction and exclude other forms of addiction, such as tobacco, gambling, eating disorders and sexual behavior. The presenters were asked to comment on:

- What are the specific hypothesis-driven biomedical and clinical research questions that need to be addressed?
- What research is needed to determine how to remove barriers to the implementation of evidence-based treatments?
- What research is required to understand the biological basis of addiction and the changes produced in the brain by drugs that can lead to addiction, in hopes of finding effective interventions to prevent addiction?

Presentations

- Dr. Kevin Conway, National Institute of Drug Abuse, presented statistics on drug and alcohol use among youth. Alcohol use was reported by 65% of 12th graders and prescription drug use by 15% of 12th graders in a 2008 survey. One important research questions is why some people are at greater risk for substance use disorders (SUD). Both genetic and environmental factors play a role and interact in complex ways. Psychiatric disorders co-occur with SUD. In one study children adopted at birth into a neutral environment had a greater chance of developing a drug problem at age 22 if their birth fathers had both a SUD and antisocial personality disorder compared with adoptees whose birth father had only one risk factor or neither risk factor. Another study, just reported in *Pediatrics*, shows that adolescents at high

genetic risk exhibited less risky behavior after participating in a preventive intervention, which points to the effect of environment in mediating genetic risks. Other important research questions are how to measure individual differences in risk and severity of addiction and what can be done to eradicate drug abuse. There are effective prevention and intervention programs, such as Communities That Care, Evidence-Based Curriculum (EBC), methadone treatment, and brief interventions in primary care. The problem is that proven approaches are not well utilized. Discussion: In response to a question from the Committee about funding gaps, Dr. Conway indicated the need to fund implementation research in order to understand the economic costs and barriers to the adoption of evidence-based interventions. Asked about the rates of SUD in the U.S. compared to other countries and if the problem may be caused by early brain damage due to environmental exposures, Dr. Conway indicated that microstudies in which individuals move to the U.S. from other countries find an increase in psychiatric disorders and SUD and therefore, it is likely that environmental factors play a role. The prevalence of SUD and psychiatric disorders varies by culture, but the association between SUD and psychiatric disorders is robust. Dr. Staiano-Coico commented that her university, like others around the country, is being overwhelmed by the increased need for psychiatric services. Funding is needed for multi-institutional research to address this issue.

- Dr. Sheri Berenbaum, Pennsylvania State University, addressed the question of what happens to the brains of college students who use alcohol. College students drink heavily. Heavy drinking impairs brain function in adults, but very little is known about its effect on adolescents. The brain develops into young adulthood, so the research questions that need to be answered include: is there a sensitive period, i.e., an age at which drinking causes more brain dysfunction, when do the brain changes become irreversible, what factors affect how a person's brain changes with alcohol use, is binge drinking particularly harmful, should binge drinking be the focus of interventions, and what is the effect of preventive interventions on brain function.
- Dr. Jenae Neiderhiser, Pennsylvania State University, summarized research on the influence of family and peers on drug use. Factors that influence the initiation and abuse of substances include marital conflict, parent-child conflict, sibling conflict, children who encourage deviant behavior among their siblings, low parental monitoring of children, and children's association with delinquent peers. Genetic influences contribute to both initiation and continued use of drugs. Only peer group delinquency is associated with continued use of drugs during young adulthood. The evidence points to the importance of preventing youth from trying drugs as the most effective strategy. The most effective prevention strategies are those that focus on improving communications within families. There is a need for continued study of how genes and environmental factors interact within the family to influence substance abuse.
- Dr. Anna Childress, University of Pennsylvania, indicated that violence, substance abuse and risk taking behavior tend to be connected. Vulnerable brains may explain why these behaviors are related. In the normal brain, the brain's frontal circuitry acts as a brake, providing for good impulse control and enabling good decision making. In a vulnerable brain, the stop circuits are not working. Individuals more likely to be at risk of having a vulnerable brain are those whose parents have vulnerable brains, teens, males and those exposed to early stress or trauma. Imaging shows how vulnerable brains over-respond to signals for rewards (such as cocaine cues) and signals for danger/threat. Imaging tools can be used to identify teens with vulnerable brains for intensive prevention interventions.

- Dr. Martin Adler, Temple University, stated that addiction is a brain disease for which there are unanswered questions, such as what happens to brain cells that causes craving, what neuronal circuits, cells and mediators in the brain are involved in addiction, and what medications can be developed to interfere with the circuits and neurons altered by addiction. The answers to these questions lie in basic, pre-clinical research. The findings of a study on rats provided an example of the effectiveness of chemokines in blocking the analgesic effect of morphine. Altering the chemokine system in the brain has the potential to block craving and the development of drug dependence. Research is needed to study this and other novel approaches to drug addiction and to study the interactions of multiple drugs. Multiple drug use is the norm for drug abusers and this is an under-funded area of research.
- Dr. Susan Amara, University of Pittsburgh, reiterated the point that addiction is a brain disease and there is a need for a basic research to provide an understanding of how drugs affect the brain in order to develop more effective therapies. A basic understanding of the effect of cannabis (marijuana) on the brain was lacking when public policies were adopted by some states to legalize the use of marijuana for medicinal purposes. There is a need for basic science research in order to gain a better understanding of the effects of amphetamines on the brain.
- Dr. Connie Pechura, Treatment Research Institute, stated that SUD, which include unhealthy substance use, abuse and addiction, are chronic health conditions, which should be treated through a continuum of care using models known to be effective for chronic illnesses. According to a 2005 survey, 52 million Americans were binge or heavy drinkers, which is indicative of unhealthy and harmful use. Research should address not only those in specialty treatment for addiction or in need of treatment, but also those whose use is unhealthy or harmful. At the identification stage on the continuum of care, health services research is needed to determine barriers to and the most effective models for implementing screening and brief interventions in primary care and other healthcare settings. At the treatment engagement stage, research is needed to determine how to get people into treatment quickly, and expand the choice of treatment options and the use of medication. At the intervention phase, research is needed to determine how to increase the use of proven, empirically supported treatments by providers, including the impact of financial incentives on adoption of these practices. In the recovery phase, we need research on models of continuing care, such as monitoring mechanisms and community support centers.
- Dr. Charles O'Brien, University of Pennsylvania, focused on the use of genetics for improving treatment outcomes. Many youth experiment with drugs, but few become addicted, and heredity plays a role in determining who becomes addicted. Naltrexone, a medication used to treat addiction, blocks opioid receptors and works well in some patients, but not in others. To determine why, candidate gene studies were conducted and these studies identified a SNP (single nucleotide polymorphism) that causes people to respond differently to alcohol. Individuals with the G allele, which is present in 20-25% of European Americans, experience significantly more euphoria and a bigger release of endorphins, when they consume alcohol. A retrospective analysis of data on relapse to treatment which was conducted at the University of Pennsylvania, showed that patients with the G allele who were randomized to naltrexone had a much lower relapse rate to treatment than patients without the G allele. This was replicated in a national sample. When people with the G allele were put on placebo (standard treatments such as AA, group therapy, cognitive behavioral therapy) they achieved a 63% response. Those that received placebo plus naltrexone achieved a 95%

response. A recent prospective study attempting to replicate this finding also found that people with the G allele on naltrexone responded much better to treatment than those who were not treated with naltrexone. If this research holds up, it may be possible to use a simple, relatively inexpensive genetic test in physicians' offices to predict response to naltrexone as a treatment for addictions.

- Leslie Hurtig, Public Health Management Corporation, highlighted the challenges that their organization experienced with implementing evidence-based practices (EBP) in community treatment programs. Providing clinical supervision, training and periodic feedback were effective strategies for overcoming barriers. Additional research is needed to evaluate the impact of clinical supervision, training, incentives, and performance improvement data on adherence to EBPs.
- Dr. Robert Turrisi, Pennsylvania State University, focused on the problem of reducing underage drinking through parent-based initiatives. The heaviest periods of alcohol use are teens and people in their twenties. People do not go into treatment until they are in their 30's on the average, which points to the need for prevention programs. Little is known about how to intervene with children according to a recent publication in *Pediatrics*. We know that parents can make a difference, if they communicate with their children and monitor their behaviors. In studies funded by the National Institutes of Alcohol Abuse and Alcoholism (NIAAA), handbooks used by parents to talk to their children about alcohol use before the children went to college were effective in reducing drinking by 50% in their children when they got to college. Research questions which need to be addressed are: what evidence-based interventions can be used to reduce abusive drinking among youth, what are the best ways to promote delivery and uptake of these interventions, what genetic and community factors affect youth alcohol abuse and response to interventions, and what other youth risk behaviours are affected by the interventions.

Discussion

Dr. Seiden commented that substance abuse behaviors are chronic and asked about data on the long term effectiveness of treatment. Dr. O'Brien responded that Penn has been conducting outcome studies for 40 years. Like people being treated for hypertension, people do well in treatment initially, some better than others because of their genetic makeup. At 3 months, 50-80% are still doing well, but the longer the follow up, the more likely they will relapse. However, relapse is not considered a failure, but instead a sign that additional treatment is needed. He follows up patients for years, at different intervals (every 2 weeks, or every 6 months, etc.) depending on the patient. He teaches families the signs of relapse so they will know when they need to get the patient back into treatment. It is important to keep in mind that addiction is a memory and causes a physical change in the brain. Therapy teaches new memories, but you cannot erase old memories. Even if someone has been drug free for 10 years, there is a chance of relapse. Dr. Staiano-Coico recommended an integrated approach and the need for early intervention. Dr. Kuller asked what approach should be used to investigate genetic factors. Dr. O'Brien responded that candidate gene studies can still be beneficial if they are done with biological endpoints, such as biochemical markers in the brain, which can be determined by MRI and PET scans. Dr. Levine asked if a reasonable approach might be to combine molecular genetics with imaging and start the studies in infancy or early childhood. Dr. O'Brien concurred with this approach. Dr. Davis commented about the fact that national funding stops at the translational level, and asked why that is and who funds human services research. Dr. Pechura

indicated that the Robert Wood Johnson Foundation, which provided over \$1 billion in funding over 15 years, has stopped funding for this research. However, NIH has increased its focus on translational research. Dr. Conway indicated that Services is one branch in his Division at NIDA and one-third of their efforts go toward this research. These studies are difficult, complicated and expensive to conduct and additional funding is needed in this area. Dr. Amara stated that federal stimulus funds (ARRA) focused on translational research. Dr. Levine commented that we have extraordinary animal models like the zebra fish and we need to think broadly about what we might learn from these models. Dr. Adler added that NIH seems to have moved from investigator-initiated research toward targeted research where NIH determines what is needed and this approach does not lend itself to discovery. He added that funds are needed in all areas – molecular, animal, human and translational. If you don't fund basic research, you will not make discoveries that can translated into new treatments. Dr. Davis asked how the state should target limited funds to obtain an impact at the end of a short time frame. Dr. Neiderhiser recommended a focus on the family, prevention, and gene-environment interactions. Dr. Turrisi recommended focusing on youth. Dr. Childress commented that, because of heterogeneity, we need the tools to identify who will respond well to various types of prevention and treatment approaches.

Act 2001-77 Requirements and Guiding Principles for Selecting Research Priorities

Dr. Potrzebowski reviewed the requirements in Act 2001-77 for revising the research priorities. The Department must establish in conjunction with the Committee the research priorities, and the priorities must be reviewed annually and revised, as needed. The priorities must include the identification of critical research areas, disparities in health status among various Commonwealth populations, expected research outcomes and benefits, and disease prevention and treatment methodologies.

The five principles adopted by the Committee to guide the selection of the priority were reviewed. According to these principles, the research priority should:

1. Address a health-related issue that has significant impact on the health of Pennsylvanians.
2. Place emphasis on a health-related issue that disproportionately affects vulnerable segments of the population.
3. Be inclusive of all populations that are at high risk for the health-related issue.
4. Focus on studies with the potential for prevention and control including the identification of risks and etiology for the health-related issue.
5. Promote collaboration among Pennsylvania institutions including smaller colleges and universities and other non-academic medical centers as well as major research institutions.

Consideration needs to be given to assure balance between the research priorities, in light of the requirement in the law that 50% or more of the nonformula funds be spent on clinical and/or health services research. If the Committee recommends a priority that is in the early stages of investigation and is primarily focused on biomedical research, the other priority should focus on health services and/or clinical research. In 2007 regenerative medicine was such an emerging area of research that many of the proposals did not contain good fundable clinical or health services research and the peer reviewers recommended that the clinical research component in one of the top ranked proposals not be funded and as a consequence funding for the regenerative

medicine project did not meet the requirement that 50% of the funds be for clinical and/or health services research. Fortunately, the proposals submitted for the other priority (violence) were almost entirely clinical or health services research so we were able to meet the legal requirement.

One of the guiding principles established by the Committee is that the research priority should address a health-related issue that has significant impact on Pennsylvanians. The leading causes of death in Pennsylvania, in rank order, are heart disease, cancer, stroke, chronic respiratory disease, unintentional injuries, Alzheimer's disease, diabetes, kidney disease, influenza and pneumonia, septicemia, suicide and liver disease. Of the 38 nonformula grants awarded to date, 26 grants directly addressed the leading causes of death. Causes of death that have not been directly addressed by past research priorities are stroke, accidents, kidney disease, and liver disease/cirrhosis.

There were three issues to be considered by the Committee in setting the research priorities:

1. Should the formula priorities remain broad and general?
2. For nonformula priorities, should the two categories: "clinical and health services research" and "other research," be combined?
3. What should be the priorities for the nonformula funds?

Formula Research Priorities for State Fiscal Year 2010-11

Mr. Torres opened the discussion of priorities for formula funds. Dr. Levine moved, followed by a second from Dr. Staiano-Coico, that the formula priorities remain the same as in past years. All Committee members voted in favor of the motion. The research priorities for the formula funds for SFY 2010-11 are:

Research priorities shall include the identification of critical research areas, disparities in health status among various Commonwealth populations, expected research outcomes and benefits and disease prevention and treatment methodologies.

The research priorities are clinical, health services, and/or biomedical research as defined in Act 2001-77. The ultimate goal of the research should be to improve health status and access. The Department should encourage, through the application process and accountability requirements, research that:

- emphasizes collaboration
- promotes business and community involvement
- increases infrastructure and research capacity
- increases the number of new investigators, new grants, new discoveries and new products
- leverages new and existing research funds, and
- leads to population-based applications that address disparities in health status among various Commonwealth populations.

An institution that receives \$400,000 or more in formula funds shall also comply with the requirements of Section 908 (c) of Act 2001-77.

Institutions receiving grants under Section 909 of Act 2001-77 shall also comply with the requirements of Section 910 of Act 2001-77.

Discussion of Nonformula Research Priorities for State Fiscal Year 2010-11

Dr. Levine moved that nonformula funding categories, (1) clinical and health services research and (2) other research, be combined. Dr. Staiano-Coico seconded the motion. The vote was unanimous in support of the motion. Accordingly, the nonformula research priority will include the following sentence: "For the purpose of priority setting and funding, the Health Research Advisory Committee recommends combining the two nonformula funding categories of clinical and health services research and other research."

Mr. Torres asked each Committee member to share their thoughts regarding next year's research priorities. Committee members then made the following suggestions and comments:

Dr. Parmacek indicated that he was impressed with the presentations on nanotechnology and substance abuse, but had some reservations about nanotechnology. It was unclear how nonformula funds would make an impact on the field, for which there appears to be a lot of ongoing work funded by a host of other enterprises. Conversely, he was impressed with the opportunities for research on substance abuse and the potential impact of research on the Commonwealth and nation. Fifty percent of the funds could be spent on clinical and health services research. He indicated his strong support for substance abuse and suggested putting all of the nonformula funds into this area.

Dr. Seiden commented that we have limited sophistication in applying the genomics of medicine, such as genomics in addiction or genomics in cancer predisposition. The ability to translate this into the clinical setting is a major unmet need.

Dr. Kuller indicated that the opportunity for translating nanotechnology was high, and presenters indicated that they could apply nanotechnology to diagnostics within the 4-year grant period. He was impressed with the ability to use the funds to bridge engineering and chemistry with medicine and move into the clinical arena. He would support nanotechnology provided that it would only fund applications for early detection and diagnostics. With regard to substance abuse, expert testimony provided evidence of the interaction of genomics and environmental exposures or treatment exposures, and this would be a valuable avenue of research that he would support. He voiced concern about using funding to evaluate addiction services.

Dr. Davis noted that the presentations demonstrated the widespread involvement of many institutions in Pennsylvania in nanotechnology. Multiple areas of science are working in an integrated way, and this field can have a real impact on medicine. The private sector can play a role in bringing nanotechnology from academics to the community. It is also an important time for growth and development in this field. With regard to substance abuse, strong arguments were made for the enormity of the problem, the progression of scientific understanding, and how the science can be directly applied to how we take care of patients. He favored putting all the

funding into one area and reluctantly would place substance abuse on the top of the list, with nanotechnology being second.

Dr. Levine proposed putting all of the funds into substance abuse. It meets all of the guiding principles which no other past priorities, with the exception of obesity, have done. It is major cause of deaths due to suicide, HIV, accidents and cirrhosis. It is predicted that the percentile of NIH funding two years hence, when the ARRA stimulus funds will end, will be at the lowest point ever. NIDA and NIAAA would suffer the most because they have very low budgets. If all of the funds are put into substance abuse, there is a real opportunity for the money to have an impact. He would like to see the focus be on identifying molecular targets in combination with the latest imaging technology to determine individual risks and provide prevention and treatment interventions based on individual risks.

Dr. Staiano-Coico agreed with the points presented by Dr. Levine and added the current economic situation in combination with the ending of the stimulus funds may exacerbate the problem of substance abuse and that Pennsylvania has incredible resources, such as Geisinger with its electronic medical record system, which can be used to assess and access patients. She suggested that it may be interesting to ask the nanotechnology presenters back in a year to see if their research has progressed to the point of clinical applicability.

Dr. Potrzebowski pointed out that grants funded in response to the RFA, would start in June 2011. Dr. Levine added that this would be approximately the time when the stimulus funding would end.

Dr. Smith-Whitley indicated that she supported the substance abuse initiative because it provides opportunities to address major health concerns, opportunities for partnerships particularly with smaller universities and community-based outreach centers, opportunities to address populations suffering from health disparities, and opportunities to look at co-morbidities, such as mental health problems and chronic pain syndrome. She added that nanotechnology should continue to be considered in the future, but the timing is not right for it now.

Dr. Seiden asked why speakers were instructed not to focus on tobacco, and indicated that nicotine has one of the highest addiction rates and that tobacco accounts for the highest total number of deaths.

Dr. Potrzebowski explained that tobacco was selected as a priority previously and the Committee has not recommended previously selected priorities again, although that can be done. Two tobacco cessation grants were funded in 2004-05. These included a motivational interviewing intervention for adolescents and an intervention to get people into treatment. The projects ended this year and the results of these grants are not available as yet.

Dr. Staiano Coico recommended that the research priority on substance abuse be broad and include both basic science as well as translational research.

Dr. Kuller commented that so much behavior is driven by the environment and it is difficult to intervene at the individual and group level with lasting long-term effects. Therefore, it is critical

to gain a better understanding of the environmental determinants and the etiology and pathogenesis of substance abuse and then apply this information to improve prevention and treatment.

Dr. Levine hypothesized that substance abuse may be due to inborn errors of metabolism and the time to recognize the potential for substance abuse is at the earliest point in life.

Dr. Kuller stated that substance abuse may be attributable to both genetics and environmental exposures early in life, such as deficiency of omega 3 fatty acid, injury, exposure to alcohol and tobacco and other factors. The point is that we need to gain a better understanding of these factors and their interactions so new approaches can be developed.

Motion

Dr. Levine moved that all of the money for next year be put into substance abuse and that the focus be on the determination of etiology and pathogenesis at the individual level at early points in life and on the basis of what was learned, we describe an intervention and then follow the intervention with health care outcomes and health services research. Dr. Potzebowski asked if all this work could be accomplished within a 4-year grant period. Dr. Levine responded that if the research makes valuable discoveries, it will be possible to secure other funding after the end of the grant. Dr. Kuller added that he would like to encourage the use of new technologies, such as MRI and PET, to look at the brain.

Dr. Davis indicated that he supported choosing one of the areas, and supported putting all of the funds into substance abuse, but he proposed that we take Dr. Levine's wording and provide this as a point of discussion for how we might frame an RFA at the next meeting. As a matter of procedure, Mr. Torres suggested that, from his notes, the majority favored substance abuse and there were several recommendations to put all of the money toward this priority. He then asked if there were any other priorities that the Committee wanted to consider. None of the Committee members proposed other priorities.

Dr. Parmacek seconded the motion. Dr. Davis asked for the motion to be repeated and he asked if the motion included the wording of the RFA. Several committee members responded that it should not. It was suggested that the motion be simply that the committee supports substance abuse as a research priority. Mr. Torres added that typically, a committee member will volunteer to draft the priority. Dr. Parmacek clarified that he supported a motion stating that we will draft a priority on substance abuse between now and the next meeting and the wording will be considered at the next meeting for discussion and a final vote. Mr. Torres asked if this revised wording for the motion was acceptable to Dr. Levine. Dr. Levine indicated that the revised wording was acceptable. Dr. Potrzebowski asked if the motion included that all of the funding be put into substance abuse. Dr. Levine stated that it was included in his motion. Mr. Torres asked for any further discussion. Dr. Staiano-Coico wanted to make sure that fundamental research was not being eliminated. Mr. Torres said that all committee members will have an opportunity to share their views on the draft. Dr. Levine offered to draft the white paper. Mr. Torres called for the vote. All were in favor of the motion that the all of the funds be put into substance abuse next year and that between now and the next meeting, a draft will be developed, which will be discussed and brought to a final vote at the next meeting.

Other Discussion

Dr. Potrzebowski asked if the Committee wanted another workshop on nanotechnology next year, as previously suggested. Dr. Parmacek said that before we go in that direction, he suggested that other area of interest was the application of genomics to medicine. What is the substantive impact of that field? There has been a lot of discussion of personalized medicine, but the same criticism given to nanotechnology can be made of genomic medicine -- the proof is in setting up well controlled clinical trials to determine its impact.

Dr. Kuller agreed that nothing substantive has evolved from genomic medicine. The real problem is the number of diseases for which there is a major genetic component, but people are not being diagnosed and receiving proper treatment, e.g., heterozygous familial hypercholesteremia.

The white paper will be submitted November 9th and then circulated to Committee members prior to the next meeting.

Next Meeting

The next meeting will be held on November 23rd in Harrisburg.

Adjournment

The meeting adjourned at 1:40 p.m.